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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,123	01/09/2002	Se-Chang Kwon	DE1325	6189

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EXAMINER	
KEMMERER, ELIZABETH	
ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,123	KWON ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 18, 19, 21-24, 26, 27* is/are rejected.

7)☒ Claim(s) *17,20 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment received 20 February 2007 has been entered in full. Claims 11-16 remain withdrawn from consideration as being directed to a non-elected invention. Claims 1-10 and 17-27 are under examination.

Withdrawn Objections And/Or Rejections

The application is now fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Therefore, the requirement set forth at p. 2 of the previous Office Action (mailed 15 November 2006) has been met.

The rejection of claims 17, 20, and 25 under 35 U.S.C. § 112, first paragraph, as set forth at pp. 3-5 of the previous Office Action (mailed 15 November 2006) is *withdrawn* in view of the DECLARATION FOR DEPOSIT OF MICROORGANISM received 20 February 2007.

The rejection of claims 1-10, 18, 19, 21-24, 26, and 27 under 35 U.S.C. § 102(e) as being anticipated by Rosendahl et al. (US 2004/0018586) as set forth at p. 6 of the previous Office Action (mailed 15 November 2006) is *withdrawn* in view of the certified translation of the Korean priority document received 20 February 2007.

The rejection of claims 1-8, 18, 19, 21-24, 26, and 27 under 35 U.S.C. § 102(b) as being anticipated by Kuga et al. as set forth at p. 5 of the previous Office Action (mailed 15 November 2006) is *withdrawn* in view of the amended claims received 20 February 2007.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 18, 19, 21-24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuga et al. (US 5362853) in view of EP 0256843A1 (published 1988; ref. OO on IDS of 15 November 2006).

As set forth in the previous Office Action (mailed 15 November 2006), Kuga et al. teach a modified hG-CSF wherein amino acid 17 is replaced with Ser. See columns 27-28, especially the sentence bridging columns 27-28. This is relevant to claims 1-4. Kuga et al. also teach DNA and an expression vector encoding the modified G-CSF at the same place. This is relevant to claims 5-8, 22-24, 27. Note that the pCF plasmid

vector base is an expression vector. See column 9, lines 9-15. Kuga et al. teach a transformed microorganism host cell, specifically *E, coli*, that comprises these DNA molecules. Col. 9, li. 9-15. This is relevant to claims 18, 19, 26. Finally, Kuga et al. teach a process for producing the modified G-CSF recombinantly using these products. *Ibid.* This is relevant to claim 21.

Kuga et al. do not specifically teach a modified hG-CSF lacking an N-terminal methionine. However, Kuga et al. do acknowledge that the addition of the N-terminal methionine is disadvantageous, and disclose enzymatic methods of removing the N-terminal methionine along with a few other N-terminal amino acids. See col. 46, li. 29-40.

EP 0256843A1 also teaches the advantage of G-CSF lacking the N-terminal methionine, and discloses how to achieve the same. See pp. 12-13 and claim 6.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Kuga et al. regarding substitution of hG-CSF so that residue 17 is Ser, by removing the N-terminal methionine residue as disclosed by EP 0256843A1 and suggested by Kuga et al., with a reasonable expectation of success. The motivation to do so can be found in both Kuga et al. and EP 0256842A1, which both discuss the disadvantage of having an N-terminal methionine.

Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuga et al. in view of EP 0256843A1 as applied to claims 1-8, 18, 19, 21-24, 26, and 27 above, and further in view of Builder et al. (US 5451660).

The teachings of Kuga et al. and EP 0256843A1 are discussed above.

Kuga et al. do not teach use of the *E. coli* thermoresistant enterotoxin II signal peptide. However, this was well known in the art at the time of the invention.

For example, Builder et al. disclose the use of the *E. coli* thermoresistant enterotoxin II signal peptide to recombinantly express a mammalian secreted protein in *E. coli.* See Example I, section B, columns 14-15. Also note suggestion of G-CSF as an appropriate protein for their disclosed method at column 8, line 22.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the G-CSF constructs of Kuga et al. by deleting the N-terminal methionine as suggested by EP 0256843A1 and using the *E. coli* thermoresistant enterotoxin II signal peptide of Builder et al. with a reasonable expectation of success. The motivation to do so can be found in Builder et al. who describe the benefits of using that particular signal sequence.

Thus, the claimed invention as a whole was *prima facie* obvious over the prior art.

Applicant's arguments (pp. 11-15, amendment received 20 February 2007) have been fully considered but are not found to be persuasive. Specifically, Applicant argues that Kuga et al. fail to disclose a sequence lacking an N-terminal methionine that can be

expressed in a microorganism such that the resulting protein is not glycosylated. This has been fully considered but is not found to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., glycosylation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Kuga et al. taken with EP 02568423A1 acknowledge the disadvantage of the N-terminal methionine.

Applicant further argues that it is not predictable that adding the leader of Builder et al. would result in successful expression in prokaryotic cells. This has been fully considered but is not found to be persuasive, since Builder et al. expressly suggests that G-CSF is appropriate in their disclosed method at column 8, line 22. Using the leader of Builder et al., the resulting G-CSF would lack the N-terminal methionine. This is also true for Builder et al.'s preferred embodiment, recombinant human IGF-I. Therefore it would have been reasonable to expect similar results.

Claim Objections

Claims 17, 20, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER